

## REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks herein, is respectfully requested. Claims 53-55, 58-60, 63-64, 66-68, 70, 72-74, 78-79, and 81-82 remain pending in this application.

Applicant's Representatives thank Examiner Minh-Tam Davis for the courtesy of a series of telephone interviews on April 21, 24 and 25, 2006, and May 4, 2006, in which various amendments to the claims were discussed.

The Examiner rejected claims 53-55, 63-64, 66-68, 70, 72-74, 78-79, and 81-82 under 35 U.S.C. § 101 as not being supported by either a specific asserted utility or a well-established utility. The Examiner also rejected claims 53-55, 63-64, 66-68, 70, 72-74, 78-79, and 81-82 under 35 U.S.C. § 112, first paragraph, asserting that one skilled in the art would not know how to use the claimed invention. These rejections are respectfully traversed.

Applicant discloses that a variant peripheral-type benzodiazepine receptor (PBR) exists in cells (Example 2). Note that the variant PBR gene disclosed in Applicant's specification has been detected in Jurkat cells and human genomic DNA (Costa et al., Mol. Pharma., 69:37 (2006) and Kurumaji et al., Am. J. Med. Genet. (Neuropsych. Genet.), 105:172 (2002)) (a copy of the abstracts of each is enclosed). Clearly, one of skill in the art in view of Applicant's disclosure would be apprised of how to use nucleic acid sequences encoding a variant PBR, as evidenced by Costa et al. and Kurumaji et al.

Applicant also discloses that PBR overexpression is associated with an aggressive phenotype in certain tumors (pages 14 and 25), although PBR is expressed in many cell types. Therefore, detection of PBR in those tumors may be useful to detect the aggressive nature of the cancer. See, e.g., Morgan et al., Br. J. Dermatol., 151:846 (2004), Maaser et al., Clin. Cancer Res., 8:3205 (2002), and Han et al., J. Receptors and Signal Transd., 23:225 (2003) (a copy of the abstracts of each is enclosed herewith).

The Examiner asserts that one cannot determine whether any of the claimed mutations exists in primary or metastatic breast cancer cells *in vivo*, due to well-known cell culture artifacts, citing numerous documents for support.

First, none of the cited documents relate to PBR. Second, as evidenced by Costa et al., Kurumaji et al., the abstract for Morgan et al., the abstract for Maaser et al., and Han et al.,

Applicant's assertion that the detection of variant PBR in cells may be useful, for instance, to detect the aggressive nature of the cancer, is credible. M.P.E.P. 2107.02(III)(B).

In this regard, the Examiner is requested to consider the Rule 132 Declaration enclosed herewith. In that Declaration, Dr. Papadopoulos, one of the co-inventors of the present application, states that variant PBR RNA is found in frozen samples of colon and breast tumor biopsies.

Moreover, the Examiner is requested to consider that prior to Applicant's filing date, there were reports of numerous mutant genes that were associated with cancer, e.g., the p60src gene, the retinoblastoma gene, and the ras gene (see Hanafusa et al., Princess Takamatsu Symp., 17:233 (1986), Weinberg, Cancer Surv., 12:43 (1992)), London et al., Princess Takamatsu Symp., 25:51 (1995), and Abrams et al., Semin. Oncol., 23:118 (1996)) (a copy of the abstract of each is enclosed herewith).

Therefore, the claims are supported by a specific asserted utility and a well-established utility.

Accordingly, withdrawal of the 35 U.S.C. § 101/§ 112(1) "utility" rejections is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date

*October 12, 2006* — *JEM*  
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12 day of October 2006.

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